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Published

With international search report.

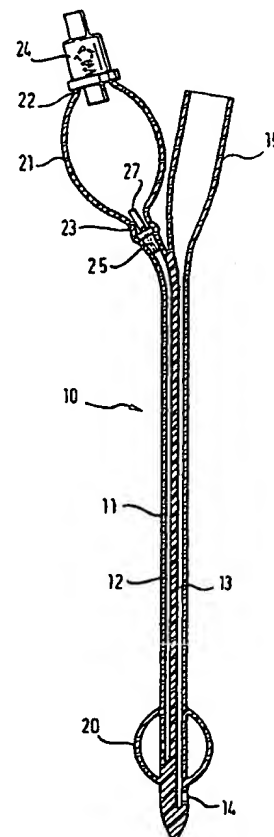
(88) Date of publication of the international search report:

23 March 2000 (23.03.00)

(54) Title: MEDICAL DEVICE WITH ELASTOMERIC BULB

(57) Abstract

In a pre-filled Foley catheter for urine drainage, the conventional clip for releasing sterile water from a bulb (21) at the proximal end of the catheter, to fill the anchor bulb (20) at the distal end of the device, is replaced by a plug (25) which has an annular portion connected to a thin stem (27) by a circle of weakness. Snapping the stem (27) from the annulus provides a tactile signal through the opaque latex lumen that the catheter has been actuated. There is no separate clip to be disposed of. The interface between the latex and the plug remains undisturbed. Further improvement in the shelf-life and convenience of use of the catheter is delivered by the use of a sleeve, which can be of shrink-wrap material, around the bulb (21) and optionally also around the drain coupling (15) of the catheter. Apparatus for placing the plug and the sleeve is also described.



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PATENT COOPERATION TREATY

PCT

REC'D 13 OCT 2000
WIPO

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 78 195 a/ea	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP99/04421	International filing date (day/month/year) 25/06/1999	Priority date (day/month/year) 25/06/1998
International Patent Classification (IPC) or national classification and IPC A61M25/10		
Applicant C.R. BARD, INC. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 6 sheets, including this cover sheet.

- ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 8 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 18/01/2000	Date of completion of this report 11.10.2000
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Abraham. V Telephone No. +49 89 2399 7463 

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP99/04421

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-22 as originally filed

Claims, No.:

1-38 as received on 26/09/2000 with letter of 26/09/2000

Drawings, sheets:

1/5-5/5 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☒ neither restricted nor paid additional fees.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/EP99/04421

2. ☐ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1. 13.2 and 13.3 is
- ☐ complied with.
- ☒ not complied with for the following reasons:

see separate sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:
- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-8,12-31,35-38.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims 1-8,12-31,35-38
	No: Claims
Inventive step (IS)	Yes: Claims 1-8,12-31,35-38
	No: Claims
Industrial applicability (IA)	Yes: Claims 1-8,12-31,35-38
	No: Claims

2. Citations and explanations

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Reference is made to the following documents:

- D1: US-A-3 675 658 (TAYLOR) 11 July 1972
- D2: US-A-3 602 226 (ERICSON) 31 August 1971
- D3: US-A-3 190 291 (FOLEY) 22 June 1965
- D4: EP-A-0 177 859 (BARNES ET AL.) 16 April 1986
- D5: EP-A-0 193 406 (BRENNEN ET AL.) 03 September 1996

IV

1. For the reasons given hereinafter, the application lacks unity of invention as required by rule 13 PCT.

- 1.1 There are three groups of separate inventions:

Invention I (claim 1): A medical device with proximal and distal ends, a fluid supply element at the proximal end, and a flow control device, the flow control device comprising a plug.

Invention II (claim 9): A medical device comprising a drainage lumen with a drain coupling at the proximal end, and an inflation fluid lumen with a fluid supply element at the proximal end, the drain coupling and fluid supply element being arranged side by side and covered by one sleeve element.

Invention III (claims 32,33): Method and apparatus for positioning a plug having a stem portion within a lumen.

- 1.2 The feature common to claims 1 and 32, 33 is a plug in a medical device comprising a stem portion and an annular portion. However, these features are described in document D4 (Fig. 2,3) as providing the same advantages as in the present application. Accordingly, these features do not involve an inventive step (Article 33(3) PCT).

Thus, the common features are not special technical features within the meaning of PCT Rule 13.2, since they make no contribution over the prior art.

Independent claim 9 relates to a catheter having at its proximal end a drain coupling and a fluid supply element, both wrapped into one sleeve. There, is no

plug specified at all.

Thus, the independent claims do not specify special technical features in the meaning of PCT Rule 13.2, which are common to all independent claims so that no technical relationship within the meaning of PCT Rule 13.1 between the different subjects exists.

V

1. Document D1 which is considered to represent the most relevant state of the art discloses the following

A Foley catheter as defined in the preamble of claim 1 of the present application (Fig. 1; col. 1, lines 50,51) wherein the control device comprises a plug (42) which blocks the lumen at its distal end and includes a parting line (44), which enables the plug to be parted into two separate parts, by manual manipulation from outside the lumen (column 2, lines 54-59).

Claim 1 differs in the following features:

the plug comprises a co-axial stem (27) and annular part (26) with a diameter at least twice that of the stem, which meet at said parting line wherein the annular part comprises a tapering portion displaying a small end and a large end, the small end being remote from the stem, wherein the annular part comprises a cylindrical portion, wherein the cylindrical portion lies between the tapering portion and the stem, in the axial direction of the plug, wherein the diameter of the cylindrical portion is greater than that of the large end of the tapering portion, including a step between the large end of the tapering portion and the cylindrical portion.

The problem to be solved by the present invention is to provide an alternate plug for controlling the fluid flow.

In document D1 the plug comprises a slit valve for controlling the fluid flow. The external force must be applied permanently in order to open the valve. A plug comprising a co-axial stem and annular part with a diameter at least twice that of

the stem, which meet at the parting line is known from D4 (Fig. 2,3). A plug comprising a cylindrical portion and a tapering portion which facilitates the positioning of the plug within a lumen appears to be an obvious design procedure and is known for example from document D5 (Fig. 2)).

A plug wherein the diameter of the cylindrical portion is greater than that of the large end of the tapering portion, including a step between the large end of the tapering portion and the cylindrical portion enhances the sealing and additionally improves the handling of the device in that the position of the plug can easily be felt from outside.

The combination of all features is neither known from, nor rendered obvious by, the available prior art.

Claim 1 therefore meets the requirements of Article 33(2)-(4) PCT.

2. Claims 2-8, 12-30 and 35-38 are dependent on claim 1 and as such also meet the requirements of Article 33(2)-(4) PCT.
3. Claim 31 also meets the requirements of Article 33(2)-(4) PCT for the same reasons given in paragraph V.1 above.

VII

1. The features of claim 31 and all the features of claim 1 should have been provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
2. According to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in document D4 should have been mentioned in the description and this document should have been identified therein.
3. In the assessment given under paragraph V 1. above the first word of the characterizing portion of claim 1 ("wherein") was neglected.
4. In the assessment given under paragraph V 3. it was assumed that in claim 31 the word "great" has been amended to "greater" (see claim 1).

C L A I M S

1. A medical device (10) with a proximal end (22) and a distal end (23), an elastomeric bulb (21) at the proximal end for storing fluid under pressure, a fluid acceptor (20) at the distal end and a lumen (12) connecting the bulb and the acceptor for flow of fluid from the bulb to the acceptor when the device is used, and including a control device (25) at the proximal end of the lumen to prevent said flow until said flow is ~~desired~~

said control device (25) comprises a plug (26) which blocks the lumen at its proximal end and includes a parting line, which enables the plug to be parted into two separate parts, by manual manipulation from outside the lumen, such parting having the effect of opening up fluid communication along the lumen from the elastomeric bulb (21) to the fluid acceptor (20) to fully fill the acceptor, and characterised in that

wherein the plug comprises a co-axial stem (27) and annular part (26) with a diameter at least twice that of the stem, which meet at said parting line wherein the annular part comprises a tapering portion displaying a small end and a large end, the small end being remote from the stem, wherein the annular part comprises a cylindrical portion, wherein the cylindrical portion lies between the tapering portion and the stem, in the axial direction of the plug, wherein the diameter of the cylindrical portion is great^{er} than that of the large end of the tapering portion, including a step between the large end of the tapering portion and the cylindrical portion.

2. Device as claimed in claim 1 wherein the bulb (21) is coated with a substance to inhibit the passage of the fluid through the wall thickness of the bulb.
3. Device as claimed in claim 2 wherein the coating is on the outside of the bulb wall thickness.

4. Device as claimed in claim 2 wherein the coating is on the inside surface of the bulb wall.
5. Device as claimed in claim 1 wherein the plug (26) carries a fluid-tight skirt membrane which extends proximally from the proximal end face of the plug.
6. Device as claimed in any one of the preceding claims, ~~wherein the acceptor is a balloon (20).~~

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7. Device as claimed in any one of the preceding claims wherein the medical device is a catheter (10).
8. Device as claimed in claim 7 wherein the catheter is a drainage catheter.
9. A medical device which is a drainage catheter (10) having a proximal end (22) and a distal end (23) and first and second lumens extending therebetween, the first lumen serving as a drainage lumen and having a fluid inflow port at its distal end and a fluid drain coupling at its proximal end, the second lumen serving to convey inflating fluid from a fluid supply element (21) at its proximal end to a fluid acceptor balloon (20) at its distal end, with the fluid supply element (21) and the fluid drain coupling arranged side by side at the proximal end of the lumen
characterised by
a sleeve which extends around both the fluid drain coupling and the fluid supply element.
10. A device as claimed in claim 9, wherein the fluid supply element is a elastomeric bulb to be inflated with said fluid, and the sleeve is of a material which is more impervious to said fluid than is the elastomeric material of said bulb (21) thereby to have the effect of slowing the rate of loss of fluid radially outwardly from the bulb (21) through the wall thickness of the bulb.
11. A device as claimed in claim 10 wherein the control device (25) comprises a plug which blocks the second lumen at its proximal end and includes a parting line, which enables the plug to be parted into two separate parts, by manual manipulation from outside the lumen, such parting having the effect of opening up fluid

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communication along the lumen from the elastomeric bulb (21) to the fluid acceptor (20) to fully fill the acceptor.

12. Device as claimed in any one of the preceding claims, wherein the acceptor (20) is made of elastomer.
13. Device as claimed in any one of the preceding claims and made of latex rubber.
14. Device as claimed in any one of the preceding claims wherein the fluid is a liquid, and the fluid supply element (21) contains said fluid.
15. Device as claimed in claim 14 wherein the fluid is water.
16. Device as claimed in any one of claims 1 to 8, 11 or and one of claims 12 to 15 as dependent on claim 11, wherein the diameter of the annular part of the plug is at least three times that of the stem.
17. Device as claimed in claim 16 wherein the annular part comprises an annulus (26) of material with a proximal end face (30) and a distal end face (28) and a bore (29) extending between the two end faces.
18. Device as claimed in claim 16 or 17, wherein said stem (27) extends proximal of the annular part, coaxially therewith and has an outside diameter substantially less than that of said annular part (26).
19. Device as claimed in claim 18 wherein the stem is friction fitted within the bore (29) of the annular part.

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20. Device as claimed in claim 18 wherein the stem (27) is integral with the annular part and joined to it by a circle of weakness (31).
21. Device as claimed in claim 20 wherein the annular part and stem are together formed as only one piece of molded polymer material.
22. Device as claimed in any one of claims 16 to 21, wherein the axial length of the annular part of the plug is greater than its largest diameter.
23. Device as claimed in any one of the preceding claims, wherein the length of the cylindrical portion is smaller than its radius.
24. Device as claimed in any one of the preceding claims, in which the tapering portion comprises a frusto-conical or substantially frusto-conical portion which has a small end which is larger than the small end of the tapering portion.
25. Device as claimed in any one of the preceding claims, in which the tapering portion comprises a frusto-conical or substantially frusto-conical portion which has a small end which constitutes the small end of the tapering portion.
26. Device as claimed in claim 25, as dependent on claim 24, wherein the tapering portion comprises first and second frusto-conical or substantially frusto-conical portions, of different cone angle, such that the diameter of the tapering portion varies along the axis at a greater rate near the small end of the tapering portion than at the large end of the tapering portion.

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27. Device as claimed in any one of the preceding claims in which the stem is cylindrical.
28. Device as claimed in any one of the preceding claims wherein the fluid supply element (21) has an open proximal end (22) closed by a filler valve (24).
29. Device as claimed in any one of the preceding claims, and which is a urinary drainage catheter.
30. Device as claimed in claim 29 wherein the catheter is a Foley catheter.
31. Plug for use as a flow control device in a medical device as claimed in any one of the preceding claims, said plug having an annular part and a stem with a diameter not more than half that of the annular part, and with a parting line where the stem joins the annulus wherein the annular part comprises a tapering portion displaying a small end and a large end, the small end being remote from the stem, wherein the annular part comprises a cylindrical portion, wherein the cylindrical portion lies between the tapering portion and the stem, in the axial direction of the plug, wherein the diameter of the cylindrical portion is great than that of the large end of the tapering portion, including a step between the large end of the tapering portion and the cylindrical portion.

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32. Method of positioning a plug within a lumen of a medical device, the method comprising the steps of:
- i. providing the plug with an annular portion and a stem, co-axial with the annular portion and having a diameter substantially less than that of the annular portion, the annular portion sealing with the lumen wall;
 - ii. presenting an open end of the lumen, for receipt of said plug;
 - iii. engaging the stem of the plug with an injector rod;
 - iv. advancing the injector rod into the lumen open end and along the lumen to the desired position within the lumen.
- 33.. Apparatus for positing a stemmed plug within a lumen of a medical device, the apparatus comprising:
- i. expansion fingers to engage and widen the open end of said lumen; and
 - ii. an injector rod to engage the stem of the plug and advance the plug into the open end and along the lumen to a desired position within the lumen.
34. Apparatus as claimed in claim 9, or any one of claims 10 to 30 as dependent on claim 9, wherein the sleeve is of shrink-wrap material.
35. Apparatus as claimed in any one of claims 1 to 8 wherein the elastomeric bulb is sleeved in shrink-wrap material.
36. Apparatus as claimed in claim 34 or 35 wherein the permeability of the sleeve material to diffusion of water therethrough is less than that of latex rubber.
37. Apparatus as claimed in claim 34 or 35 wherein the shrink-wrap material is polystyrene.

AMENDED SHEET

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38. Apparatus as claimed in any one of claims 34 to 37 wherein the shrink-wrap sleeve incorporates a tear strip.

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INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 78 195 a/ea	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/EP 99/ 04421	International filing date (day/month/year) 25/06/1999	(Earliest) Priority Date (day/month/year) 25/06/1998
Applicant C.R. BARD, INC. et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☒ **Unity of invention is lacking** (see Box II).

4. With regard to the title,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☒ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

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☐ None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/EP 99/ 04421

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

1. Claims: 1-36, 39-43

1.1 Claims: 1,2-8,12-35,36,40-43

A medical device with proximal and distal ends, a fluid supply element at the proximal end, and a flow control device, the flow control device comprising a plug having a parting line enabling the plug to be separated into two separate parts for fluid communication.

1.2 Claims: 9,10-35,39,41-43

A medical device comprising a drainage lumen with a drain coupling at the proximal end, and an inflation fluid lumen with a fluid supply element at the proximal end, the drain coupling and fluid supply element being arranged side by side and covered by one sleeve element.

2.Claims: 37,38

Method and apparatus for positioning a plug having a stem portion within a lumen.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 99/04421

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61M25/10 B25B27/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M B01F F16L B25B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 190 291 A (FOLEY) 22 June 1965 (1965-06-22) column 3, line 3 - line 50 figures 1,3,6	1,2,4, 6-8, 34-36
A	---	11-14
X	US 4 248 236 A (LINDER) 3 February 1981 (1981-02-03) column 3, line 41 -column 4, line 6 figure 2	9
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Date of the actual completion of the international search

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